



WEST VIRGINIA SECRETARY OF STATE
KRIS WARNER
ADMINISTRATIVE LAW DIVISION

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 Office of West Virginia
 Secretary Of State

**NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE AND FILING WITH THE LEGISLATIVE RULE-
 MAKING REVIEW COMMITTEE**

AGENCY: Medicine TITLE-SERIES: 11-10
 RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No
 RULE NAME: 11-10 Practitioner Requirements for Accessing the West Virginia Controlled Substances
 Monitoring Program Database

PRIMARY CONTACT

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CITE STATUTORY AUTHORITY: W.Va. Code § 60A-9-5a(c)

EXPLANATION OF THE STATUTORY AUTHORITY FOR THE LEGISLATIVE RULE, INCLUDING A DETAILED SUMMARY OF THE EFFECT OF EACH PROVISION OF THE LEGISLATIVE RULE WITH CITATION TO THE SPECIFIC STATUTORY PROVISION WHICH EMPOWERS THE AGENCY TO ENACT SUCH RULE PROVISION:

W.Va. Code § 60A-9-5a(c)

IS THIS FILING SOLELY FOR THE SUNSET PROVISION REQUIREMENTS IN W. VA. CODE §29A-3-19(e)? Yes

IF YES, DO YOU CERTIFY THAT THE ONLY CHANGES TO THE RULE ARE THE FILING DATE, EFFECTIVE DATE AND AN EXTENSION OF THE SUNSET DATE? Yes

DATE eFiled FOR NOTICE OF HEARING OR PUBLIC COMMENT PERIOD:

DATE OF PUBLIC HEARING(S) OR PUBLIC COMMENT PERIOD ENDED:

COMMENTS RECEIVED:

(IF YES, PLEASE UPLOAD IN THE COMMENTS RECEIVED FIELD COMMENTS RECEIVED AND RESPONSES TO COMMENTS)

PUBLIC HEARING:

(IF YES, PLEASE UPLOAD IN THE PUBLIC HEARING FIELD PERSONS WHO APPEARED AT THE HEARING(S) AND TRANSCRIPTS)

RELEVANT FEDERAL STATUTES OR REGULATIONS:

WHAT OTHER NOTICE, INCLUDING ADVERTISING, DID YOU GIVE OF THE HEARING?

SUMMARY OF THE CONTENT OF THE LEGISLATIVE RULE, AND A DETAILED DESCRIPTION OF THE RULE'S PURPOSE AND ALL PROPOSED CHANGES TO THE RULE:

This rule sets forth the requirements for Board of Medicine licensees and registrants to obtain and maintain access to the West Virginia Controlled Substance Monitoring Program database.

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE RULE:

This rule protects public safety by providing protocols and requirements for when licensees and registrants of the Board must access and review controlled substance prescription data for patients being treated with controlled substance medications.

SUMMARIZE IN A CLEAR AND CONCISE MANNER THE OVERALL ECONOMIC IMPACT OF THE PROPOSED LEGISLATIVE RULE:

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

B. ECONOMIC IMPACT ON SPECIAL REVENUE ACCOUNTS:

C. ECONOMIC IMPACT OF THE LEGISLATIVE RULE ON THE STATE OR ITS RESIDENTS:

D. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2026 Increase/Decrease (use "-")	2027 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost			
Personal Services			
Current Expenses			
Repairs and Alterations			
Assets			
Other			
2. Estimated Total Revenues			

E. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT):

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

Jamie C Frame -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

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TITLE 11
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF MEDICINE
SERIES 10

PRACTITIONER REQUIREMENTS FOR ACCESSING THE
WEST VIRGINIA CONTROLLED SUBSTANCES MONITORING PROGRAM DATABASE

11-10-1. General.

1.1. Scope. -- This rule sets forth the requirements for licensees and registrants of the West Virginia Board of Medicine regarding accessing the West Virginia Controlled Substance Monitoring Program database.

1.2. Authority. -- W.Va. Code § 60A-9-5a(c)

1.3. Filing Date. -- ~~May 9, 2022.~~

1.4. Effective Date. -- ~~June 1, 2022.~~

1.5. Sunset Provision -- This rule shall terminate and have no further force or effect upon August 1, ~~2027~~ 2037.

11-10-2. Definitions.

2.1. As used in this rule, the following words and terms have the following meaning:

2.1.a. “Administering” means the direct application of a drug to the body of a patient by injection, inhalation, ingestion or any other means.

2.1.b. “Benzodiazepine” means a class of controlled substance medications that produce sedation, induce sleep, relieve anxiety and prevent seizures and which are generally approved to treat anxiety disorder, insomnia, seizures, social phobia, and panic disorder.

2.1.c. “Board” means the West Virginia Board of Medicine as described at W. Va. Code §30-3-5.

2.1.d. “Controlled substance” means a drug that is classified by federal or state law in Schedules I, II, III, IV or V, as defined in W. Va. Code Chapter 60A, Article 2.

2.1.e. “CSMP” means the West Virginia Controlled Substances Monitoring Program repository and database.

2.1.f. “DEA registration identification number” means the federal Drug Enforcement Administration registration identification number issued to a practitioner.

2.1.g. “Dispensing” means the preparation and delivery of a drug to an ultimate user by or pursuant to a lawful order of a practitioner, including the prescribing, packaging, labeling, administering or compounding necessary to prepare the drug for that delivery.

2.1.h. “Medical records” means records including the medical history and physical examination; diagnostic, therapeutic and laboratory results; evaluations and consultations; treatment objectives;

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discussion of risks and benefits; informed consent; treatments; medications (including date, type, dosage and quantity provided); instructions and agreements; and periodic reviews.

2.1.i. “Opioid” means controlled substance medications which are natural and semi-synthetic derivatives of the opium poppy, as well as similar synthetic compounds that have analgesic or pain relieving properties because of their effects in the central nervous system. Opioids include, but are not limited to, codeine, morphine, hydromorphone, hydrocodone, oxycodone, methadone, and fentanyl.

2.1.j. “Patient” means a person presenting himself or herself for treatment who is not considered by the practitioner as suffering from a terminal illness.

2.1.k. “Practitioner” means a physician, podiatric physician or physician assistant who possesses a valid DEA registration identification number and who is licensed by the Board pursuant to Articles 3 or 3E of Chapter 30, or holds an interstate telehealth registration issued by the Board pursuant to W. Va. Code § 30-1-26.

2.1.l. “Providing” means prescribing, dispensing or administering medication.

2.1.m. “Terminal illness” means an incurable or irreversible condition as diagnosed by the attending physician or a qualified physician for which the administration of life-prolonging intervention will serve only to prolong the dying process.

§11-10-3. Practitioner Requirements for Obtaining and Maintaining Access to the CSMP.

3.1. Practitioners who prescribe or dispense Schedule II, III, IV, or V controlled substances shall register with the CSMP and obtain and maintain online or other electronic access to the program database. Compliance with the provisions of this section must be accomplished within 30 days of the practitioner obtaining a new license or registration or within 30 days of re-licensure or re-registration.

3.2. Licensees shall be required to certify compliance with the provisions of this section when renewing a license. The Board may conduct an audit to verify compliance therewith.

11-10-4. General Rules for Practitioners for Patients Not Suffering from a Terminal Illness.

4.1. The provisions of this section only apply to a practitioner’s prescribing, administering or dispensing of Schedule II controlled substances, opioids, or benzodiazepines to a patient that the practitioner does not consider to be suffering from a terminal illness.

4.2 A practitioner shall apply for and receive capability to access the CSMP providing a patient any Schedule II controlled substance, any opioid, or any benzodiazepine.

4.3. Before initially providing any Schedule II controlled substance, any opioid, or any benzodiazepine to a patient a current practitioner shall access the CSMP to determine whether the patient has obtained any controlled substance reported to the CSMP from any source other than the current practitioner within the twelve month period immediately preceding the current practitioner’s encounter with the patient.

4.4. The practitioner shall promptly document the initial CSMP data review in the patient’s medical record. Documentation must include the date the practitioner accessed the patient’s CSMP record, a dated copy of the CSMP report or a list of all controlled substances reported to the CSMP as dispensed to the

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patient within the preceding twelve months, and the practitioner's rationale for providing the patient Schedule II controlled substance(s), opioid(s), and/or benzodiazepine(s).

4.5. If a practitioner-patient relationship continues and the course of treatment includes the continued prescribing, dispensing or administering of any controlled substance, the practitioner shall access the CSMP at least annually to determine whether the patient has obtained any controlled substances reported to the CSMP from any source other than the current practitioner within the twelve month period immediately preceding the date of access. The date of access and any controlled substances from any other source other than the current practitioner reported to the CSMP within such twelve month period immediately preceding the date of access shall be then promptly documented in the patient's medical record by the current practitioner, with rationale for continuing provision of the controlled substance by the current practitioner.

4.6. A practitioner may review a patient's CSMP data more frequently than annually. However, a practitioner must document each CSMP data review in the patient medical record. Documentation must include the date the practitioner accessed the patient's CSMP record, a dated copy of the CSMP report or a list of all controlled substances reported to the CSMP for the patient from any source other than the practitioner, and the practitioner's rationale for discontinuing or continuing to provide controlled substances to the patient.

4.7. A practitioner who is providing a patient controlled substance medication shall review a patient's CSMP data whenever the provider has a specific concern regarding controlled substance abuse, misuse, or diversion of controlled substances by the patient.

11-10-5. Discipline and Administrative Penalties.

5.1. Any practitioner who fails to comply with this rule is subject to Board disciplinary proceedings for failing to perform any statutory or legal obligation placed upon the practitioner and unprofessional, unethical, and dishonorable conduct, pursuant to W. Va. Code § 30-3-14, W. Va. Code § 30-3E-17, and/or the rules of the Board.

5.2. Any practitioner who fails to comply with the requirements described in W. Va. Code § 60A-9-7(f) or (g) shall be subject to the respective administrative penalties set forth in those subsections. All fines collected pursuant to those subsections shall be transferred by the Board to the Fight Substance Abuse Fund created under W. Va. Code § 60A-9-8.